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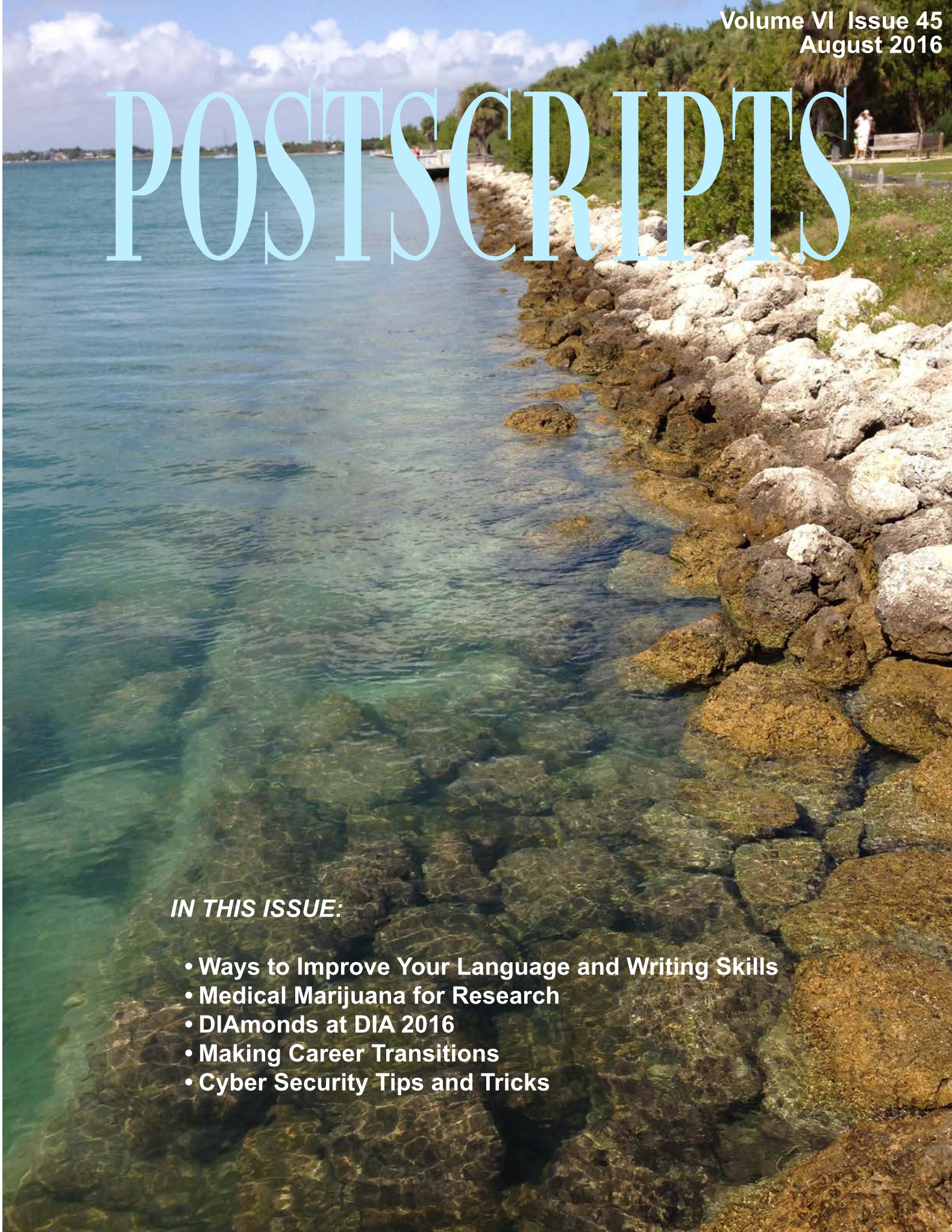
POSTSCRIPTS



IN THIS ISSUE:

Official publication of the American Medical Writers Association Pacific Southwest Chapter

POSTSCRIPTS

AIMS AND SCOPE

Postscripts is the official publication of American Medical Writers Association (AMWA) Pacific Southwest chapter. It publishes news, notices, job postings, and articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical and regulatory writing, scientific writing, publication planning, continuing medical education (CME) and physician/patient education, social media, current regulations, ethical issues, medical writing training and certification, and good writing techniques.

MISSION STATEMENT

The mission of *Postscripts* is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, *Postscripts* publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; and book and journal summaries. Additionally, to promote career and networking needs of the members, *Postscripts* includes news and event notices covering AMWA Pacific Southwest Chapter activities.

SUBSCRIPTION: *Postscripts* is published monthly except in January and July. The magazine is available as an open access publication and is currently distributed online only.

INSTRUCTIONS FOR CONTRIBUTORS: We consider articles on any topic of interest to our membership. It is helpful to look at the past December issues for year-end tables of contents, and to browse past issues for style and type of articles published. We welcome contributions from AMWA members. Non-member contributions are generally by invitation by the Editor or any member of the Chapter's Board. Detailed instructions are provided in the December 2015 issue, *Postscripts* 2015;5(39):204.

ADVERTISING: *Postscripts* is an advertising-free magazine. However, articles describing products and services relevant to medical writers, editors and communicators may be considered or solicited. As a service to our members, they may submit advertisements for their services or products for free. Please contact the Editor.

WEBSITES:

Chapter website: http:// www.amwa-pacsw.org
AMWA website: http://www.amwa.org
Postscripts: http://issuu.com/postscripts

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In this issue. . .

ACKNOWLEDGEMENT

Many thanks to Clare Prendergast, MA (Norton Thoracic Institute, Phoenix, Arizona) for copyediting and proofreading this issue. Clare's bio and her contact information appear in the April 2016 issue of *Postscripts*.

COVER:
Ocean Shore. By Karen Braga. 2016. http://morguefile.com/p/1007285.

From the President's Desk

If you're returning from your summer vacation, welcome back; and if you're about to take your last trip of the summer, have fun! When you return, please do consider the great educational and networking opportunities available to you at the major AMWA events planned for late summer and fall:

- The AMWA Pacific Southwest 2016 Symposium, hosted again by Amgen, is now scheduled for September 10 in Thousand Oaks. We have put together an exciting lineup of presentations that will include an overview of health economics and outcomes research (HEOR) opportunities for medical writers, practical tips for using Word and templates, and document-sharing programs. Registration will open soon, and a networking lunch and all presentations will be free due to the generous support of Amgen.

- The AMWA national meeting is now called the Medical Writing and Communication Conference (http://www.amwa.org/conference), and will be held this year in Denver from October 5 through 8 at the Sheraton Denver Downtown Hotel. Our annual chapter dinner is scheduled for Friday October 7, and you will be receiving more information about registration for the dinner soon. In addition to all the educational content offered, the Denver meeting will be a great place to reconnect with chapter members who live in our geographically diverse area (Southern California, Arizona, and Southern Nevada).

As mentioned previously, we received an excellent response to our email gauging interest in a chapter mentoring program, and we are hoping to begin it soon with a webinar for mentors and mentees in November. More details will follow soon. Please email me at president@amwa-pacsw.org if you have not yet contacted us about joining our program as a mentor or mentee.

Our August issue begins with a review of the Drug Information Association (DIA) National 2016 meeting in Philadelphia penned by our editor, Ajay Malik. Rebecca Anderson discusses the availability of marijuana for medical research, and Hope Lafferty presents some techniques to help stimulate and improve your writing skills (not surprisingly, reading is at the top of the list). Lycely Sepulveda summarizes the excellent guide to career transitions that Marilyn Allison presented at our March 2016 meeting at Becton Dickinson, and Chip Reuben presents some valuable techniques for preserving the security of your computer systems and data. Our monthly news and updates from the FDA are provided by Lamia Merabet. Finally, we have summaries of two recent local meetings: Eileen Lai-Hoshino reports on our chapter's (delicious) networking brunch in May in Orange County, and Roberta Alexander reports on a joint event (San Diego Clinical Research Network and San Diego Chapter of the Association of Clinical Research Professionals) to discuss patient-centric strategies in clinical research of Alport Syndrome, an orphan genetic disease that affects the kidneys.

Hope to see you soon in Thousand Oaks, Denver, or both!

Susan

Susan Vintilla-Friedman, MWC
President, AMWA Pacific Southwest Chapter

DIAmonds at DIA 2016 Meeting in Philadelphia

Summer is for travels: Travel to festivals and fairs; travel to the beach; travel to national parks; travel across state borders; travel to meetings in another time zone—where did your travels take you? This summer, the destination for over 7,000 medical writers, regulatory scientists, clinical operations professionals, patient advocates and other drug development experts was Philadelphia for the annual meeting of the Drug Information Association (DIA). This nerdy lollapalooza is billed as the largest annual gathering of its kind in the world.

What was special about this year's DIA meeting was a series of "DIAmond Sessions" on *conversations on today's priorities*.[1] These sessions brought together thought leaders from government agencies, academia, industry, and patient advocacy organizations for coffee-table-style discussions on topics that impact drug development, approval, and patient access to medicines.

The very first DIAmond session, "International Regulatory Convergence, Collaboration, and Cooperation" was chaired by Emer Cooke of the European Medicines Agency (EMA). Also on the panel were Robert Califf, Commissioner of the Food and Drug Administration (FDA), Tatsuya Kondo, Chief Executive of Japan's Pharmaceuticals and Medical Devices Agency (PMDA), Jonathan Mogford of United Kingdom's (UK) Medicines and Healthcare Products Regulatory Agency (MHRA), Health Canada's Anil Arora, who is also the chair of the International Council of Medicines Regulatory Agencies (ICMRA), and leaders from the regulatory agencies of Ireland, Brazil and Australia. As DIA said in its tagline, it was a *gathering of global perspectives*.

The panel provided an eagle-eye view of the challenges to bringing safe and effective medicines to market, patient access, safety and drug supply chain integrity, and tremendous progress being made to overcome these challenges.

As expected, some challenges are unique to a particular regulatory region—take Brexit for example. As Cooke pointed out, it is anybody's guess how Brexit will affect the working relationship between MHRA and EMA or FDA; it is business as usual at present, though regulators on both sides of the English Channel are hoping for cooler heads to prevail in the end. The US has its own unique challenge of the ongoing opioid epidemic which got a small mention from Dr Califf who said, "I don't wish this on anyone else." Overall, the panel spent most of its time talking about challenges (unique or common) and areas of collaboration as below:

- **Clinical evidence generation and keeping up with technological innovation**: The FDA is investing a lot of resources to increase the knowledge base of its workforce viz-a-viz new technologies; creating mechanisms to utilize electronic health records (EHRs), claims data, and clinical and payer registries to support evidence generation; and developing guidelines to use companion diagnostics and health-IT data supporting drug applications.
- To address apparent **regulatory hurdles for regenerative medicines**, EMA did a look-back study meeting with industry, payers and patient groups to identify barriers. EMA got an earful—regulatory requirements are onerous for regenerative medicines—and it is now developing policies to rectify this.
- Both the FDA and the EMA have nondisclosure agreements that allow them to get on a common teleconference call and discuss a new drug application and share their analyses and conclusions. *This is regulatory convergence in the trenches*. It is a wonderful step towards **increasing efficiency of drug approval regimes across agencies** which has been welcomed by the industry and patient groups.
- **Shrinking the clinical development timeline is a priority** across the regions, and strategies are being implemented to accelerate development of promising and innovative medicines targeting serious diseases: The FDA has Breakthrough Therapy Designation (BTD), Japan has SAKIGAKE (*lit*. "pioneer" or "pathfinder") Designation, while EMA has implemented PRIority MEdicines (PRIME) program. These programs provide advice on Phase 3 program and regulatory support (and mentorship). The agencies are sharing their experience and learning from each other how to improve these programs.
  - — For the industry, the priority programs mean that they must beef-up their regulatory strategy with upfront planning to prepare applications for all 3 agencies when Investigational New Drug (IND) Application is filed.
- The **mutual reliance between agencies** also extend to the PMDA. The FDA has started accepting audits and inspections of Japanese companies by the PMDA. Similar cross-agency collaboration between the FDA and the EMA is also being developed.
- **Supply chain integrity** is another area of active collaboration. The medicine on a store shelf in the US may have its API originating in China or India, the packaging/carton may have come from Taiwan, the drugs may have been packaged in

Vietnam, and then shipped to the US. Being able to monitor such a complex supply chain is no easy task. There are approximately 2,500 API manufacturers in China; it is impossible for the FDA to inspect all these facilities. This is where ICMRA comes in.

—ICMRA is a voluntary organization consisting of 22 regulatory agencies with WHO as observer. The priorities of ICMRA are (a) to ensure global supply chain integrity, (b) to create protocols for crisis management and collective response to global threats, eg, Zika, and (c) to develop common tools to collect and share pharmacovigilance signals from across the world.

In another DIAmond session, "Making Outcomes-Based Health Care Possible," the panel discussed a need for tools to analyze data collected through EHRs and other sources and to create guidelines for using this data as a robust substitute for (or complement) randomized clinical trials (RCTs)—the data are already out there! These initiatives are designed to develop tools and procedures for capturing post-market, off-label, EHR, registry (from payers, companies and regions) and other population-level data and combine that with data from clinical studies by applying "adaptive design." *Why this shift from RCTs to population outcomes data*? The panel offered the example of childhood leukemia: today, we know how to treat it, but we learned this during post-licensing and not through RCTs.

Franklin Roosevelt / Fireside Chats.
Source: https://www.loc.gov/loc/lcib/0804/newdeal.html

Convergence of data

Currently the outcomes data exists in silos, eg, payers' registries that do not talk to each other or to industry/academia-sponsored registries. There are other "strange" issues, such as, payers can't legally look at their own registry data, even though they pay for these drugs. These are the type of issues all stakeholders are trying to address. Being able to analyze all the evidence in real time is central to the notion of "evidence not being a static entity" and is critical to making an argument in support of the value of new medicines and ensuring access (in spite of the high price tag). Gigi Hirsch, MD, of MIT Center for Biomedical Innovation, who was on the panel, is at the forefront of bringing adaptive design to clinical evidence generation. Her group is pressure-testing models and procedures with the goal of ultimately coming up with ICH-type guidelines and standards.

These DIAmond sessions (of which were 8) were akin to the FDR's Fireside Chats: sincere, honest, frank, and up-close conversations in a big living room, exuding hope and optimism grounded in collaboration across all agencies. Just like the Ohio and Missouri rivers converging into the Mississippi river, the regulatory agencies are also slowly but surely coalescing into an international regime where GMP and other audits and, one day, drug approvals by one agency will be honored across regions. When it comes to trust and collaboration, regulatory agencies and their partners in the industry and patient organizations are way ahead of their political masters.

Outside the DIAmond sessions, there was a plenty of action at the DIA lallapalooza: There were up to 17 concurrent sessions to choose from; there was a series of "Innovation Theaters" where companies could present new tools and services; and town hall meetings held by FDA (CDER and CBER), EMA, PMDA, and Health Canada.

Medical writers as agents of change

As a medical writer, I came back with the view that regulatory guidelines are continuously evolving, requiring adaptation in how we create protocols and develop reports. The role of patients is continuously expanding: Their input is being sought at protocol development, patient-reported outcome (aka PRO) measures are becoming more important during drug review and later during negotiations with payers for reimbursement. The documents being developed by medical writers are increasingly being mandated to be placed in public domain, requiring the companies to have processes in place to be able to anonymize patient data, and yet have a language that is also accessible to the informed patients. The nature of clinical/medical writing is undergoing an evolution. This makes a strong case for continued engagement and learning through such national meetings and educational offerings by organizations, such as AMWA. The conversation will continue at the upcoming AMWA's annual "Medical Writing & Communications Conference" in Denver this October. Hope to see you there!

Notes and Sources

1. The theme of 2016 DIA meeting was "conversations on today's priorities".
2. Selected abbreviations: ICH = The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, CDER = Center for Drug Evaluation and Research, CBER = Center for Biologics Evaluation and Research

Everything's Going to Pot

By Rebecca J Anderson, PhD, AMWA Pacific Southwest Chapter Member

You can now legally buy marijuana for your personal/medical use over-the-counter in 23 states and DC, and in some states, for recreational use, too. The medical marijuana franchise keeps growing with several more states getting ready to vote on legalizing pot this November. Yet, there are still many hurdles when it comes to sourcing pot for research purposes.

Researchers are left in the cold, because the feds still list marijuana as a Schedule I drug. By definition, Schedule I substances (e.g., heroin and LSD) have no accepted medical use. But this legal definition doesn't square with accumulating evidence for marijuana treatment of nausea, pain, and glaucoma. Researchers suspect that pot (or some of the compounds in it) may also treat other medical conditions such as cancer, fibromyalgia, epilepsy, and autism—if only they could get a good and steady supply of the stuff and do proper studies, including randomized placebo-controlled trials.

Even in states where ***medical*** marijuana is legal, scientists have to wait months or years—and jump through multiple hoops—to conduct their ***medical*** marijuana research. Until recently, they had to obtain separate approvals from DEA, PHS, FDA, and NIDA[1] before they could get their hands on "legal" marijuana to inject into mice or to sprinkle on cells in a petri dish.

Once the scientists get signatures from all the federal agencies, they are authorized to use only pot that comes from the government's official repository at the University of Mississippi. Last year, NIDA authorized shipments to just 8 researchers.

As always, creative and driven scientists find work-arounds within the bounds of the law and regulations. John W. Huffman, a chemist at Clemson University, did just that. He made synthetic compounds that were structurally similar to marijuana and bound to the same biological receptors but were not on the DEA's Schedule I list. Some of those compounds (JWH-018 in particular) were more potent and/or more selective than marijuana itself.

Huffman was well-intentioned, and his research provided valuable insight into marijuana's mechanisms of action. But when he published his work (including the chemical structures and synthesis methods), some enterprising Walter Whites began making the compounds in their basements and selling them, à la t, under names like K-2 and Spice.

It would have been so much better for everyone if Huffman had not faced such stiff barriers to using natural cannabinoids. Many black-market JWH-018 users unfortunately ended up in the emergency room—or the morgue. (In case you're wondering, DEA now lists JWH-018 as a Schedule I drug.)

Meanwhile, celebrities including Whoopi Goldberg, Willie Nelson, and Snoop Dogg have merrily moved along, launching their own personally branded pot products. Of course, such celebrity endorsements are nothing new. Recent excavations of pipe fragments at Stratford-upon-Avon indicate that even Shakespeare was a pothead. (Gives new meaning to "A Midsummer Night's Dream.")

But cheer up. Things are finally looking brighter for researchers—maybe not psychedelically brighter, but better.

Last year, the White House took a baby step toward simplifying the approval process. Researchers who need more pot to complete their approved studies can apply for a waiver, rather than going through the entire approval process again.

In addition, the DEA is now reviewing three petitions, along with requests from several senators including Bernie Sanders, urging reclassification of marijuana to at least Schedule II. Legislators of both parties have also been quietly slipping provisions in Congressional Appropriations bills that would loosen federal marijuana laws, at least in states where pot is legal. (Who says Congress isn't doing stuff?)

That would make it easier for researchers, because they could buy their research marijuana without fear of prosecution and would be less dependent on the Mississippi repository. To coin a phrase, "The times, they are a-changing," and we (medical writers) should be pleased about that. More marijuana research means more research papers, and more research papers means more work for us—clear-headed professional writers.

But, then again, Brexit taught us that anything can happen in an election. So, don't hold your breath—unless you're sucking a bong.

[1]Drug Enforcement Agency, Public Health Service, Food and Drug Administration, and National Institute on Drug Abuse

REBECCA J ANDERSON, PhD, is a freelance medical writer and the author of two books, *Nevirapine and the Quest to End Pediatric AIDS* and *Career Opportunities in Clinical Drug Research*. Prior to medical writing, Dr. Anderson managed research and development projects for twenty-five years in the pharmaceutical/biotech industry. She holds a PhD in pharmacology from Georgetown University. She lives in Southern California, and when she is not writing, she absorbs the sights and sounds of the West Coast's rich culture and heritage. She can be reached at rebeccanderson@msn.com.

Praxis

By Hope J Lafferty, AM, ELS, AMWA Southwest Chapter Member

Tapping Into Language

During one of my coaching sessions, a workshop participant really pushed me on how she could get better at her writing. She was raised in China, has lived in the States for the past decade, and now works as an oncology researcher. Like all my workshop participants, she submitted a writing sample, and I was impressed by how wonderfully short her sentences were—a rare feat in many academic circles.

Her writing was clean, concise, and well organized. In the workshop, she had a great sense of humor and appeared rapt and interested in the material. I've worked with a number of nonnative English speakers, and neither her writing sample nor her self-presentation declared to me that she was not fluent in American English.

Still, when we sat together in our coaching session, we focused on improving her level of comfort about writing in English and discussed the stark differences in the structure of sentences in Chinese compared with English. She articulated that English is short and direct and that Chinese has a more winding, illustrative quality. She also admitted that writing short, clear sentences has been the prime focus of her English writing. Again, very well done.

Like all my clients, she sought ways to improve. During the workshop, I referred to all my usual academic texts, and of course, she wondered what other journals she might read to get really used to American English writing.

Journals? For engaging American prose? As examples of fluid speech for nonnative speakers? I have my favorites, but this client deserved more. "Have you ever read *The New Yorker*?" She hadn't. She wasn't familiar with it. She wrote down "New York Magazine" and I quickly corrected her (my apologies to the good writers at *New York*). I explained that *The New Yorker* not only has many great articles on science and medicine, but that it's also a way to see how Americans use language—sentence structure, vocabulary, imagery—in a way that scientific journals just can't. I told her that I start my day reading from that magazine.

Then I told her that she needs to write more just to practice writing stories in English. I suggested *Wild Mind*—she giggled with excitement about the title—by Natalie Goldberg. We discussed how the book has a lot of writing prompts to help writers to either observe the moment or reflect on stories in their lives. "We all remember when our mothers wore that special orange lipstick," I said, and her eyes lit up like I uncovered a secret. She was off and running.

So think about the ways that you learned to start writing well. Consider how you start your writing day. Consider some resources that you might resurrect to keep improving your craft.

HOPE J LAFFERTY, AM, ELS, has run her writing and training consultancy, Hope Lafferty Communications, since 2009. Over her career, she has worked as a writer in radio, high tech, engineering, instructional design, and medical research. Hope completed certificates in medical writing and editing from AMWA and the University of Chicago and in training from the Association for Talent Development. She serves as AMWA Annual Conference Chair-Elect and President-Elect of the Board of Editors in the Life Sciences (BELS). When she's not webcasting, podcasting, or otherwise modeling good writing practice, she takes road trips with her musician husband and comedian dog. Connect with Hope at hope@hopelafferty.com.

Woman Reading. National Media Museum.
Source: https://flic.kr/p/5eF532

Cyber Security Tips and Tricks

Chip Reuben, MS, AMWA Pacific Southwest Chapter Member

In an era of increasing dependence on tools online, nefarious hackers walk alongside diligent workers. Included here is a brief summary of security measures useful for protecting your data. These recommendations are not exhaustive, but many of them are quite rigorous:

1) Minimize dependence on electronic devices capable of handling data. Your devices are quite difficult to hack when they are not powered on. Include data on others' servers (eg, Facebook) with discretion. Disconnect or power down storage media as much as possible.

2) Avoid engaging in Internet sessions that are sensitive in nature (eg, with your bank, client, or employer) while using public WiFi. Always used a secured (ie, encrypted) connection using a protocol of sufficient security (eg, WPA2). WEP IS NOT SECURE! Also, use a virtual private network (VPN) if possible. Use secure websites when available. You can always attempt to do so manually by typing https://... in front of the URL. The "s" stands for "secure". Finally, use a quality browser such as Firefox or Chrome, avoiding Internet Explorer unless its use is essential. Internet Explorer is weak on security, and ranks low on HTML5 compliance. Become familiar with the security features of your chosen browser.

3) Every operating system (OS) should have ample antivirus protection. A Windows OS requires an antivirus program, whose definitions need to be updated regularly to protect against the most recently implemented threats.
   a. Windows 7 + Microsoft Security Essentials (MSE) + Malwarebytes Anti-Exploit. Do a full scan with MSE initially and be sure to enable "real-time protection" under "settings". After that, the "Quick" scan is all that is needed. Anti-Exploit is an added security measure.
   b. Windows 10+ Malwarebytes Anti-Exploit. With Windows 10, the MSE tool is integrated in the operating system via Windows Defender. As with Windows 7, you may also add Anti-Exploit for added protection.
   c. Ubuntu. This operating system is a more user-friendly flavor of Linux, which is inherently quite secure largely because of its chmod utility that regulates access to every file on the OS. Ubuntu allows for easy encrypted backups.
   d. Mac has also been inherently secure because, like Linux, it is based on UNIX. But things are changing in this regard, especially with iOS, which has seen a spike in hacks over the past few years.

4) In addition to standard antivirus protection, the following steps can be taken:
   a. When you click links on the web and in emails, be sure the action of the click actually matches the written description on the link. In Windows you can check for this match my simply right-clicking on the link and checking under Properties to ensure that the link matches the written description of the link.
   b. For highly rigorous antivirus procedure, you can always run a downloaded file (eg. a program) through the following steps in which you will ultimately check the results of your downloaded file by way of an entire battery of antivirus utilities (including the ones mentioned above):
   i. Use a Checksum Utility (obtain a copy of MD5 & SHA Checksum Utility from Cnet[1]) to obtain a unique hash (identifier) for the file.
   ii. Open the file in the Checksum Utility program and copy the MD5 value it generates. You can probably also use one of the SHA values, but the

MD5 should be sufficient.

iii. Paste the MD5 number into Google and inspect the search results. You may find an entry for Virustotal (www.virustotal.com), which aggregates results from a large set of antivirus utilities. If no Virustotal entry exists, you should upload the file to that site for an analysis. Additionally, you can use that site to check the safety of a URL.

iv. Read the results of the Virustotal analysis. This metasearch checks scores of many antivirus results, and therefore is highly sensitive for malicious files, and produces a sizeable proportion of false positives. For example, Virustotal gives a false positive for the MD5 & SHA Checksum Utility! In some of these cases, however, Virustotal will generate a note that the file is probably safe. Additionally, check the Google search results of your hash identifier for a Kaspersky White List result.

In summary, the best defense against falling victim to cyber criminals is to minimize your dependence and use of online tools; and to exchange sensitive data over public WiFi. Additionally, it is always best to store your data under your own roof on a device that you can power down. Be sure to use current antivirus and anti-malware software, or a UNIX-derived OS. Finally, be critical of the sources you visit while surfing the web for information.

LINKS:

1. http://download.cnet.com/MD5-SHA-Checksum-Utility/3000-2092_4-10911445.html

CHIP REUBEN, MS, whose artwork forms our Chapter's banner (see the journal's masthead page), is a senior medical/scientific writer with over a decade of experience in regulatory and scientific writing and editing, analyzing data, cutting-edge medical education, and publication development. Visit www.chipreuben.com and his LinkedIn page to learn about the services provided by Chip Reuben Medical/Scientific Writing. Chip is also an education advisor for Data Science and Artificial Intelligence for the Los Angeles AI Deep and Machine Learning Meetup Group. He received his masters in molecular biology with focus on cardiovascular pharmacology and immunology, from San Diego State.
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News and Updates from the FDA

Lamia Merabet, MS, MBA, AMWA Pacific Southwest Chapter Member

Voluntary withdrawals and recalls were issued by by Alere, PharmaTech and Talon Compounding Pharmacy.

A few **advisory committee meetings** have been scheduled from August to October, as detailed below.

Selected FDA Announcements

Date	Announcement
07-11-16	**Alere to Initiate Voluntary Withdrawal of the Alere INRatio® and INRatio®2 PT/INR Monitor System**. Following a collaborative process with the U.S. Food and Drug Administration (FDA), Alere Inc. (NYSE:ALR) will be initiating a voluntary withdrawal of the Alere INRatio® and INRatio®2 PT/INR Monitoring System. Alere is working with the FDA to determine the most appropriate timing for product discontinuation and will provide guidance on transitioning patients to an alternate solution to allow them to continue anti-coagulation monitoring in the least disruptive manner possible. Although Alere is confident that the software enhancements it developed over the course of the past two years, and that were submitted to the FDA at the end of 2015 effectively address this issue, the FDA notified the company that it believes the company's studies do not adequately demonstrate the effectiveness of the software modification and advised Alere to submit a proposed plan to voluntarily remove the INRatio® device from the market. In light of this input from the FDA and the company's business considerations, Alere has recently determined to voluntarily remove the INRatio system from the market.[1]
07-15-16	**PharmaTech LLC of Davie, FL, the manufacturer of the Rugby® - branded product, issues an immediate release of information for a Voluntary Nationwide Recall of Diocto Liquid Distributed by Rugby Laboratories Due to Product Contamination.** The company learned of the potential issue through the receipt of two isolated complaints regarding this product. FDA has informed PharmaTech and Rugby that it received several adverse event reports of Burkholderia cepacia infections in patients. Additionally, some of these reports identify liquid docusate products manufactured by companies other than PharmaTech. Use of docusate sodium liquid contaminated with B. cepacia may result in serious infections that could be life-threatening in patients with compromised immune systems and in patients with chronic lung conditions such as cystic fibrosis. As part of its commitment to patient safety, Rugby® Laboratories is working with PharmaTech LLC to notify customers who may be in possession of Diocto Liquid NDC 0536-0590-85; 50 mg/5 mL for all lots within the expiration period. Diocto Liquid is used as a stool softener and is packaged in one pint (473 mL) bottles. All lots with NDC 0536-0590-85 are included in the recall. Diocto Liquid was distributed nationwide to **wholesale and retail facilities including hospitals and pharmacies**.[2]
07-21-16	**Talon Compounding Pharmacy ("*TCP*") of San Antonio, Texas**, is voluntarily recalling all lots of lyophilized HCG and sermorelin aseptically compounded and packaged by TCP and that remain within expiry due to the Food and Drug Administration's ("FDA") concern over a lack of sterility assurance. Although no complaints of illness or injury have been received regarding the recalled lots, administration of a sterile drug product intended to be sterile that is compromised can result in health hazards including risk of serious infection or other complications. The sterile products were distributed to patients and providers nationwide between January 18 and July 18, 2016. The recall does not pertain to any other medication prepared by TCP or to any other form of HCG/sermorelin (oral tablets).[3]

Selected FDA Approvals (Drugs)

Syndros®
Insys Therapeutics Inc. Chandler, Arizona

Syndros (dronabinol) was approved on July 1st, 2016 under the New Drug Application (NDA) Number 205525.6
Last year, the company submitted an NDA for a synthetic, orally administered, liquid formulation of the cannabinoid THC (dronabinol) - administered in the form of a sublingual spray. The U.S. Food and Drug Administration (FDA) extended the Prescription Drug User Fee Act (PDUFA) date from April 1st, 2016 to July 1st, 2016 for the drug.
After the submission of the original NDA, the company submitted information relating to the rescheduling of Syndros under the Controlled Substances Act - this was a big enough amendment to the NDA that the FDA exercised its option to extend the PDUFA date in order to provide them more time to complete the review.[7]

Xiidra®
Shire U.S Inc. Lexington, Massachusetts

Xiidra (lifitegrast ophthalmic solution) was approved on July 11th, 2016 under the NDA # 208073 for the treatment of signs and symptoms of dry eye disease.
Xiidra is the first medication in a new class of drugs, called lymphocyte function-associated antigen 1 (LFA-1) antagonist, approved by the FDA for dry eye disease. It was classified as a priority review drug.
"Normal tear production is needed for clear vision and eye health," said Edward Cox, M.D., director of the Office of Antimicrobial Products in the FDA's Center for Drug Evaluation and Research. "This approval will provide a new treatment option for patients with dry eye disease."[8]

Selected FDA Approvals (Devices)

Belviq XR®
Arena Pharmaceuticals GmbH. Zofingen, Switzerland.
Distributed by Eisai Inc. Woodcliff Lake, New Jersey

Belviq XR (Lorcaserin hydrochloride) was approved on July 15th, 2016 under the NDA # 20852 as a new form release or new manufacturer.[9]
FDA approves Belviq to treat some overweight or obese adults
The U.S. Food and Drug Administration initially approved Belviq (lorcaserin hydrochloride), as an addition to a reduced-calorie diet and exercise, for chronic weight management for use in adults with a body mass index (BMI) of 30 or greater (obese), or adults with a BMI of 27 or greater (overweight) and who have at least one weight-related condition such as high blood pressure (hypertension), type 2 diabetes, or high cholesterol (dyslipidemia).
Belviq works by activating the serotonin 2C receptor in the brain. Activation of this receptor may help a person eat less and feel full after eating smaller amounts of food.[10]

Absorb GT1
Abbott Vascular. Santa Clara, California

On July 5th, 2016, the FDA approved the first fully absorbable stent to treat coronary artery disease. The Absorb GT1 Bioresorbable Vascular Scaffold System (BVS), which releases the drug everolimus to limit the growth of scar tissue, is gradually absorbed by the body in approximately three years.
"The FDA's approval of the Absorb GT1 BVS offers a new treatment option for individuals who are candidates for angioplasty, but would prefer an absorbable device rather than a permanent metallic coronary stent," said Bram Zuckerman, M.D., director of the division of cardiovascular devices at the FDA's Center for Devices and Radiological Health.
Coronary heart disease is responsible for about 370,000 deaths each year in the U.S., according to the National Heart, Lung, and Blood Institute. The Absorb GT1 BVS is manufactured from a biodegradable polymer called poly(L-lactide), which is similar to materials used in other types of absorbable medical devices, such as sutures. The device's absorption by the body gradually eliminates the presence of foreign material in the artery once the stent is no longer needed. After absorption, there are only four very small platinum markers embedded in the walls of the artery, which help cardiologists identify where the Absorb GT1 BVS was originally placed.[11]

Tecnis® Symfony IOL
Abbott Medical Optics, Inc. Santa Ana, California

The U.S. Food and Drug Administration approved on July 15th, 2016 the first intraocular lens (IOL) that provides cataract patients with an extended depth-of-focus, which helps improve their sharpness of vision (visual acuity) at near, intermediate and far distances.
"While IOLs have been the mainstay of cataract treatment for many years, we continue to see advances in the technology," said Malvina Eydelman, M.D., director of the Division of Ophthalmic and Ear, Nose and Throat Devices in the FDA's Center for Devices and Radiological Health. "The Tecnis Symfony Extended Range of Vision IOL provides a new option for patients that may result in better vision across a broader range of distances."
Traditional monofocal IOLs have been limited to improving distance vision. The Tecnis Symfony IOL improves visual acuity at close, intermediate and far ranges and, therefore, may reduce the need for patients to wear contact lenses or glasses after cataract surgery.
The approval is based on a review of results from a randomized clinical trial comparing 148 cataract patients implanted with the Tecnis Symfony IOL to 151 cataract patients implanted with a monofocal IOL. Among other recommendations, the device is not intended for use on patients who have had previous trauma to their eye.[12]

QuantideX gPCR BCR-ABL IS Kit
Asuragen, Inc. Austin, Texs

On July 22nd, 2016, the U.S. Food and Drug Administration (FDA) allowed marketing of the first nucleic acid-based quantitation test for use during treatment of chronic myeloid leukemia (CML) patients. The FDA reviewed data for the QuantideX qPCR BCR-ABL IS Kit, manufactured by Asuragen, Inc., through the de novo classification process, a pathway to classify medical devices of low- to moderate-risk that are novel and not substantially equivalent to any legally marketed device.
CML is a rare disease that causes the body to make too many white blood cells, due to a genetic abnormality that produces the BCR-ABL gene (also known as the Philadelphia Chromosome) not found in normal cells. CML mostly affects older adults and is rarely seen in children.
The QuantideX qPCR BCR-ABL IS Kit uses blood specimens from patients with CML to measure the amount of BCR-ABL, which can be used to estimate the amount of leukemia cells in a patient when treated with BCR-ABL targeted therapies.
BCR-ABL testing is a critical tool to help clinicians determine whether patients are responding to treatment for CML; however, it is not intended for the diagnosis of CML. Also, it is a prescription device.[13]

Advisory Committee Meetings

Date	Committee
09/30/16	The Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting to discuss, make recommendations, and vote on information regarding a de novo request for the SEEKER Newborn Screening System (SEEKER System), by Baebies, Inc. The SEEKER System consists of the SEEKER Analyzer, the SEEKER 4-Plex Assay Kit, the SEEKER Cartridges, the Spot Logic software, and quality control materials; it uses digital microfluidic technology to measure multiple lysosomal enzymatic activities quantitatively from newborn dried blood spot specimens. The proposed Indication for Use for the SEEKER System device, as stated in the de novo request, is as follows:

Enzyme (abbreviation)	Disorder
α-L-iduronidase (IDUA)	Mucopolysaccharidosis Type I (MPS I) disease
α-D-glucosidase (GAA)	Pompe disease
β-glucocerebrosidase (GBA)	Gaucher disease
α-D-galactosidase A (GLA)	Fabry disease

The SEEKER System is intended for quantitative measurement of the activity of multiple lysosomal enzymes from newborn dried blood spot specimens. Reduced activity of these enzymes may be indicative of a lysosomal storage disorder. The enzymes measured using the SEEKER 4-Plex Assay Kit and their associated lysosomal storage disorder are listed in the following table.
Reduced activity for any of the four enzymes must be confirmed by other confirmatory diagnostic methods.[14]

08/16/16 Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.
The committee will discuss and make recommendations regarding the appropriateness of clearing or approving of over-the-counter (OTC) diagnostic tests for the detection of pathogens causing infectious diseases, focusing on respiratory and sexually transmitted infections (STI). Currently, there are no OTC diagnostic tests for infectious diseases cleared or approved by CDRH. The committee will evaluate the risks and benefits to individual patients and to public health associated with clearing or approving OTC diagnostic tests for infectious diseases. Serious risks such as false negative results, false positive results, patient loss to medical follow-up, and the impact on surveillance of reportable infections will be addressed. Potential benefits such as reduction of infection transmission and increased access to testing will be discussed as well. The committee will also make recommendations on clinical study design, analytical study design, and acceptable performance criteria applicable to respiratory and STI diagnostic devices.[15]

09/15-16/16 Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee, the Drug Safety and Risk Management Advisory Committee, and the Pediatric Advisory Committee Meeting Announcement
The purpose of this public advisory committee meeting is to discuss the appropriate development plans for establishing the safety and efficacy of prescription opioid analgesics for pediatric patients, including obtaining pharmacokinetic data and the use of extrapolation.[16]

10/19/16 Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee
The committee will discuss the efficacy and safety of new drug application (NDA) 201656 (desmopressin), 0.75 mcg/0.1 mL and 1.5 mcg/0.1 mL nasal spray, submitted by Serenity Pharmaceuticals, LLC, for the proposed treatment of adult onset nocturia.[17]

ACKNOWLEDGEMENT: This article collates news and updates from the FDA website. Refer to the websites listed under references for full reports.

WEBLINKS AND REFERENCES

- For additional information on approvals, including labeling revisions, tentative approvals, efficacy supplements with supporting clinical data, manufacturing changes or additions, or chemistry; new strength, see http://www.fda.gov/NewsEvents/Newsroom/default.htm
- For additional information on recalls, market withdrawals, and safety alerts, see http://www.fda.gov/Safety/Recalls/default.htm
- For information on current drug shortages, see http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
- For information on drugs to be discontinued, see http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
- For Orange Book drug product list additions or deletions, see http://www.fda.gov/Drugs/InformationOnDrugs/ucm086229.htm

[1]http://www.fda.gov/Safety/Recalls/ucm510746.htm
[2]http://www.fda.gov/Safety/Recalls/ucm511525.htm
[3]http://www.fda.gov/Safety/Recalls/ucm512680.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
[4]http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm500404.htm
[5]http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm511411.htm
[6]http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails
[7]http://seekingalpha.com/article/3985762-insys-therapeutics-hoping-syndros-blockbuster-marijuana-ticket
[8]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm510720.htm
[9]http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails
[10]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm309993.htm
[11]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm509805.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
[12]http://www.accessdata.fda.gov/cdrh_docs/pdf16/den160003.pdf
[13]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm511446.htm
[14]http://www.fda.gov/AdvisoryCommittees/Calendar/ucm503539.htm
[15]http://www.fda.gov/AdvisoryCommittees/Calendar/ucm508939.htm
[16]http://www.fda.gov/AdvisoryCommittees/Calendar/ucm486846.htm
[17]http://www.fda.gov/AdvisoryCommittees/Calendar/ucm507636.htm

LAMIA MERABET, BS, MS, MBA, is a member of the AMWA Pacific Southwest chapter and a Postscripts columnist on regulatory trends. She narrated several networking events and discussions including “To Borrow a Page from the Freelancers Book.” Lamia is a Quality and Regulatory professional at Arianne Corp. handling international projects on diagnostics and pharmaceutical compounds. Her career spans the fields of clinical research, medical writing, safety reporting, post-market surveillance, and regulatory compliance in pharma and medical devices. She earned her MS in Clinical Pharmacology from Henri Poincaré University (Nancy, France), and her MBA in Healthcare Administration from National University (San Diego, California). At the San Diego Regulatory Affairs Network (SDRAN) Program Committee, she broadcasts keynote speakers. She can be reached at LamiaMerabetProBono@gmail.com and via LinkedIn https://www.linkedin.com/in/lamiamerabetclinicaltrialfda

Implementing Patient-Centric Strategies in a Natural History Trial: A Case Study

Roberta Alexander, PharmD, PhD, Exagen Diagnostics, Inc, Vista, California

The San Diego Clinical Research Network (SDCRN) (http://theclinicalresearchconnection.com/) and the San Diego Chapter of the Association of Clinical Research Professionals (ACRP) (http://www.acrpnet.org/) co-organized an event on June 21st, 2016 at the Scripps Green Hospital in San Diego to discuss patient-centric strategies in clinical research. The speaker was Jacqui Blem, Senior Director of Clinical Operations at Regulus Therapeutics (http://regulusrx.com/). Regulus' technology focuses on microRNA, which are short, non-coding RNA sequences that interfere with RNA translation and ultimately regulate protein synthesis. Regulus' approach aims at modulating the function of microRNAs that are altered in human disease; this technology may be helpful in treating diseases caused by abnormal gene expression. Regulus has several clinical programs in hepatitis C and in Alport Syndrome. Jacqui shared with the audience her experience in conducting a natural history study in Alport syndrome, highlighting the patient-centricity of the study.

Jacqui Blem

What is Alport Syndrome?

Alport Syndrome is an orphan genetic disease affecting approximately 5,000 patients in the US. Three mutations in the gene that codes for collagen type IV have been identified in these patients. The disease manifests itself at a very early age with kidney disease, hematuria and proteinuria, and eventually, end-stage renal disease (ESRD). Dialysis and kidney transplantion are common in patients with Alport Syndrome in their 20s and 30s. Hearing loss and eye disease occur early in life as well. The disease is usually diagnosed by pediatric nephrologists; however, diagnosis is difficult—especially if no family history exists—because of the low incidence and slow progression of the disease. Regulus is developing a microRNA therapy for Alport Syndrome, RG012, which gained orphan drug designation by the FDA and the EMA. Given the rarity of the disease and the paucity of clinical trials in Alport Syndrome, Regulus recognized the importance of better understanding the disease and its progression before testing RG012; this led to the initiation of the natural history study, which was the focal point of Jacqui's talk.

What is a natural history study?

A natural history study, as the name suggests, is designed to study the history of disease progression. It is not an interventional study and there is no investigational treatment administered to the patient. Rather, patient visits are conducted to measure clinical parameters and biomarkers over time. The study Regulus is carrying out follows patients with Alport Syndrome every 12 weeks for a period of 2 years; kidney function is measured over time, and biomarkers are measured to better understand the disease and the possible response to therapy.

How do you make this natural history study patient-centric?

Especially when working on orphan diseases, you need to put the patient at the center of your activities, because there are not many patients to begin with. The first hurdle in a study like this is, indeed, patient recruitment. To increase patient participation, Regulus tried to make the study visits as easy as possible for the patients.

Regulus has 15 sites all over the globe to recruit just 150 patients, and is working closely with the Alport Syndrome Foundation to promote awareness via social media and other outlets. Flexibility of diagnosis is important for proper recruitment in an orphan study: although Alport Syndrome is a genetic disease that can be diagnosed with a genetic test, Regulus also allows the inclusion of patients who have been diagnosed clinically or because of disease history. They also offer free genetic testing—which may not be covered by insurance in the US—to the participants! Although recruitment challenges are to be expected, the global nature of this study posed additional unexpected, challenges. Regulus decided to have frequent visits (12 weeks is a short period of time, especially for a slow-progressing disease…) and decided to measure glomerular filtration rate, which is a lengthy and cumbersome test that can be quite an inconvenience for many patients. On the other hand, the 24-hour urine collection turned out not to be a big challenge: patients were given nice insulated backpacks in which to carry their urine from home to hospital, and they did not mind it!

Because there are only a few specialized centers for Alport Syndrome, in-person visits every 12 weeks are inconvenient, time-consuming, and costly for most patients. The cost issue was solved by Regulus reimbursing the patients and their caregivers for travel expenses. Payments and travel arrangements are done by an independent agency to safeguard patient privacy and to comply with HIPAA regulations. Different countries have different rules for patient reimbursement, which creates a challenge in a global study; in addition, in some countries debit cards are widely used, while in others they are not, adding to the difficulty of the reimbursement program.

To increase compliance and decrease travel, Regulus implemented a home nursing system via a global company. Nurses visit patients at home, perform routine tests and physical exams, as well as collect clinical information. This program did, however, present some challenges. For example, China does not have a home nursing services; thus, Chinese patients need to live relatively close to the site if they wish to participate in the study. In some countries, nurses cannot perform what in the US is called a "physical exam," so the study terminology needed to be changed. In other countries, nurses cannot manipulate dry ice; an arrangement with a courier had to be put in place to circumvent this problem. One key opinion leader did not want their patients to be visited at home by an outside nurse, while a certain hospital wanted to use their own nursing service instead of the global service contracted by Regulus.

Challenges notwithstanding, the study is going well, and the Alport Syndrome patients are excited to participate in a study that furthers the knowledge and understanding of their disease.

ROBERTA VEZZA ALEXANDER, PharmD, PhD, is the Associate Director of Clinical Research and Medical Affairs at Exagen Diagnostics, Inc. where she designs and oversees the company's clinical studies. Dr. Alexander transitioned recently in the diagnostics space, as she spent most of her career in drug discovery working in the pharmaceutical industry. She holds a PharmD and a PhD from the University of Perugia, Italy, and came to the USA for a postdoctoral fellowship at the University of Pennsylvania. She has been living in San Diego with her husband since leaving Philadelphia, and loves to walk on the beautiful beaches of Southern California. She can be reached via LinkedIn: www.linkedin.com/in/robertavalexander/

Summary prepared by Lycely Sepulveda, PhD, AMWA Pacific Southwest Member*

Making successful career transitions: it's all about connecting the dots

1 Start with the end in mind.

- Determine your career goal.
- Write the goal in a job-oriented manner.
- Match the goal to possible careers.
- Research feasible paths to reach the goal.

2 Recognize transferable skills.

- Learn the difference between the current and the potential position.
- Understand the skills from the current or past jobs that could transfer to the new position.
- Perform a skills gap analysis.

3 Find ways to fill in the gaps.

- Be open to new experiences and actively learn from them.
- Take a project simply to learn something new.
- Embrace enriching lateral movements.
- Gain experience through volunteering.
- Join professional societies and resource groups.

4 Grow your emotional intelligence.

- Know the perceptions others may have of someone in your current position.
- Use emotional intelligence to understand emotions and manage actions.
- Learn to name the emotions but do not exhibit them.
- Develop self-awareness and assume positive intent.

continued on next page . . .

*The author thanks Marilyn Allison, PhD, Director of Curriculum Development at CareFusion (now Becton Dickenson), San Diego, for permission to use her slides for preparing this infographic.

5 Seek feedback on your plan.

- Use feedback as a powerful learning experience.
- View all feedback as a gift.
- Request open, honest and constructive feedback.

Feedback checklist:

- WHAT specifically do you need feedback on?
- WHY do you need feedback?
- WHO could you ask for feedback?
- WHERE would be a good place to ask?
- WHEN would be a good time to ask?
- HOW should you ask for feedback?

6 Grow your professional network.

- Go to face-to-face meetings to build relationships.
- Attend conferences.
- Use lunch as a way to network.
- Volunteer to learn and meet new people.

Set up information interviews to:

- Investigate a new professional area.
- Explore desirable skills and experiences.
- Obtain visibility with people in the field.
- Expand your list of resources.
- Discover how a typical day looks like.
- Inquire about typical projects and assignments.
- Ask about how success is measured.
- Learn what people like the most/least about the job.

7 Map your career development plan.

- Create a plan that is specific, measurable and realistic.
- Restate the career goal.
- List the obstacles.
- Identify people who can support you.
- Make small changes that can help you move forward.
- Build one action into your daily work life.
- Work on a longer-term action item for the new career.

8 Embrace change and write your own story.

- Envision yourself in the new environment.
- Know where you are and where you want to be.
- Build the story that tells how your knowledge, education, and experience prepared you for the new position.
- Connect the dots that build your story and share it.

Allison, M. Making Successful Career Transitions. Presented at: AMWA Pacific Southwest Career Development Event; March 2016; San Diego, CA. Summary prepared by Lycely Sepulveda, PhD.

LYCELY SEPULVEDA, PhD, has over 20 years of biomedical communication experience in various institutions. After completing her PhD in Microbiology from Michigan State University, Lycely applied her technical communication, project management and publication planning skills to lead multi-site and international Molecular Biology, Infectious Diseases and Biotechnology projects. Lycely is an independent consultant who leverages her vast research, teaching, compliance and executive experience to identify and prioritize key deliverables to support productive outcomes at every stage of the project's lifecycle. Lycely enjoys hiking on the Southern California trails with her family and she can be reached at lycely@gmail.com.

AMWA Networking Brunch in Orange County: Career Goals and Opportunities over Short Ribs

Eileen Lai-Hoshino, MS, MPH, MBA, Member, AMWA Pacific Southwest Chapter

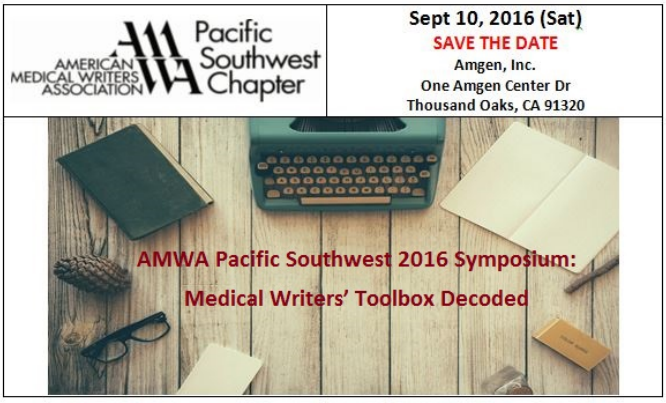
It was a delicious way to network on May 15, 2016 as AMWA members came together in Anaheim, California to have brunch, connect, and meet new colleagues. Everyone enjoyed the Italian-inspired brunch buffet at Chef's Catering, a favorite local restaurant. Attendees dined on specialties such as spinach frittatas, Osso Bucco beef short ribs, and Italian pastries while discussing career goals and opportunities.

The purpose of the brunch was two-fold: 1) to create a stronger community of medical writers in Orange County, CA and 2) to provide an opportunity for new and aspiring medical writers to connect and learn from seasoned writers. I found this informal brunch meeting to be a great way to meet more experienced writers and learn about the areas for potential career opportunities. I really learned a lot and made some great contacts. This event also attracted potential AMWA members such as Bianca Marcolino, a staff medical writer at Medtronic who said, "I would definitely attend another AMWA event. It's great opportunity to network and connect with an incredible group of professionals."

This brunch follows another successful, local happy hour event that was held on February 2, 2016, which was organized by Heather Oliff, a freelance medical writer based in Orange County. Both events are part of AMWA's Pacific Southwest Chapter's effort to address the need for more events and networking opportunities across the broader geographic Southern California area . According to the chapter's president, Susan Vintilla-Friedman, organizing a local happy hour is an easy way to meet writers in your neighborhood, and the chapter leadership is eager to help members plan and publicize these events.

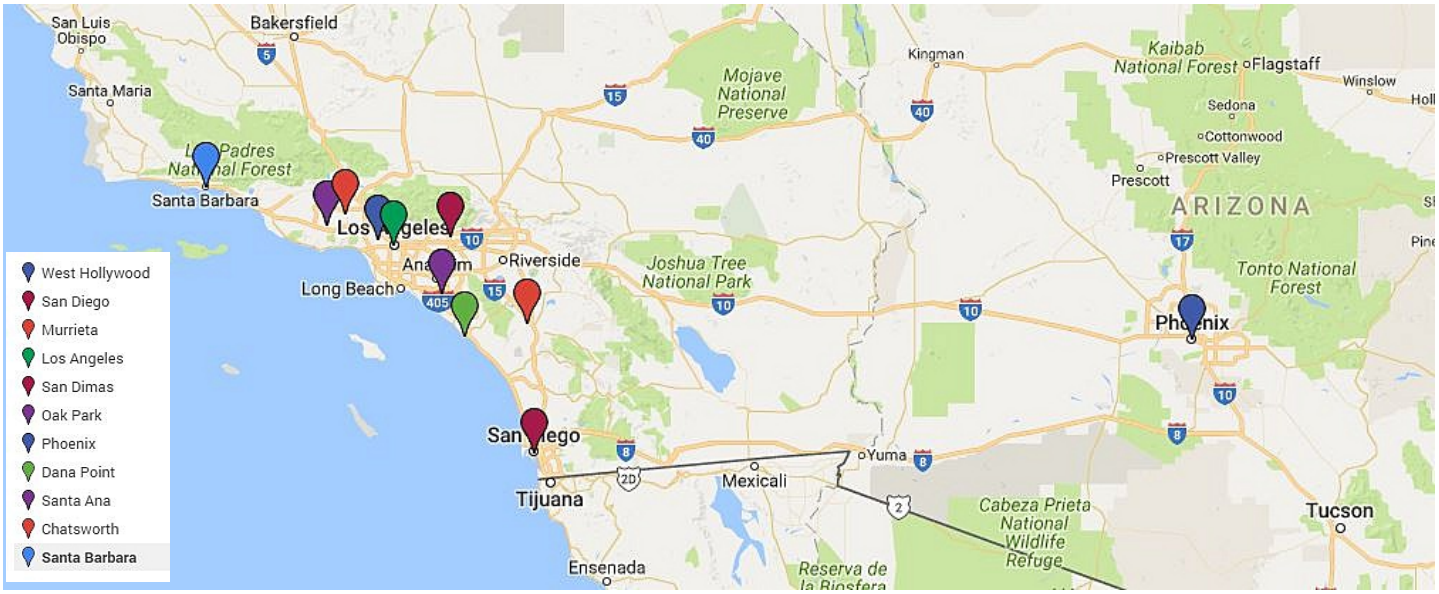
Be sure to check the AMWA Pacific Southwest calendar of events (http://www.amwa-pacsw.org/upcoming-events.html) for upcoming events in and around your local area. If you would like to organize an event in your area, please contact Susan Vintilla-Friedman at president@amwa-pacsw.org, and if you're in Orange county, I'm happy to organize another fun brunch get-together 2.0.

EILEEN LAI-HOSHINO, MS, MPH, MBA is an experienced healthcare professional with experience in both the medical and business fields. She has worked in the clinical environment as a licensed medical professional (PA-C) and management consultant in strategic planning, marketing, performance management and training design. She holds a Masters of Medical Science, an MBA in health care marketing strategy and an MPH in healthcare policy and economics. She can be reached at elai06@gsb.columbia.edu



AMWA Pacific Southwest Chapter Warmly Welcomes Our New Members

Aaron Mason – West Hollywood
Alessandra Blasina – San Diego
Allison Kissell – San Diego
Cathy Serrano – Murrieta
Charlene Barroga – San Diego
Dina Halwani – Los Angeles
Harsh Sancheti – San Dimas
Jennifer Pilgrim – Los Angeles
Karin Beloussow – Oak Park
Lynda Orescanin – Phoenix, AZ
Megan Clancy – Dana Point
Michael Howell – San Diego
Monica Vazquez – Santa Ana
Nidia Garcia – Chatsworth
Zhiyun Guan – Santa Barbara



List courtesy of Gail Flores, PhD, AMWA Pacific Southwest Chapter membership coordinator.
Email: member-coordinator@amwa-pacsw.org

Upcoming Chapter Events

Aug 25 Sep 02 Sep 10 Oct 14

AMWA Pacific Southwest Chapter Lunch (Monthly) Teleconference
Occurs First Friday of the month, 12:00—1:00 PM Pacific time

Hosted by Donna Simcoe, Past President of the Chapter
Dial in number: 706-913-1155
Participant code: 0204157# (or from your iPhone: 706-913-1155,0204157#)
Free. Open to members and non-members.

- **August**: Summer break! No monthly teleconference.
- **Friday, September 2**: We will discuss how to make the most of the 2016 AMWA Medical Writing & Communication Conference in Denver, Colorado, October 5-8. Details to come.
- **Friday, October 14**: Recap of the 2016 AMWA Medical Writing & Communication Conference.

Thursday, August 25, 2016, 12:00—1:30 pm, Webinar!

Technology Solutions for Publication Planning: A Webinar with Pubshub™

Agenda

- Review of Publication Planning and role of Medical Writer
- Create familiarity with PubsHub publication management tools—PMSolution™ and Journals&Congresses™
- Live demonstration which includes 1) System navigation and user access levels, 2) Author collaboration including capturing version history, 3) Initiating workflows and providing primary and support documents, 4) Journals&Congresses™, and 5) Reports that help manage projects
- Q&A and Feedback Session

Cost: Free
Registration details coming soon to your email Inbox!

Saturday, September 10, 2016, 10:00 AM—3:45 PM.

Medical Writers' Toolbox Symposium

Agenda

- Options, Templates, and Electronic Markup: A Word Skill Set for Complex Documents – Maggie Norris, BSc, ELS (aka WordWitch™), of Fine Print Publication Services LLC.
- Document management systems and MS Word Templates – Ajay Malik, PhD, of Intercept Pharmaceuticals Inc. and Donna Simcoe, MS, MS, MBA, CMPP, of Simcoe Consultants Inc.
- An Overview of Health Economics and Outcomes Research (HEOR): The Next Great Opportunity for Medical Writers – Julie Gegner, PhD, of Amgen Inc.
- Q & A, Networking

Location: Amgen Inc. One Amgen Center Dr, Building 24 Conference Center Auditorium
Thousand Oaks, CA 91320
Cost: Free (courtesy of Amgen)
Registration and additional details coming soon!

What's Happening at AMWA National

AMWA 2016 Medical Writing & Communication Conference
Register at www.amwa.org/conference

New this year – Workshops will be held before and after the general conference activities. Note: BOD meeting will be on Saturday, so there may be a conflict there, but otherwise workshops do not conflict with general sessions or networking events.

CORE Reference
AMWA partnered with EMWA to create the CORE Reference, a user manual to help medical writers navigate relevant guidelines as they create clinical study report (CSR) content. http://www.amwa.org/core

AMWA Online Learning
Our catalog of online learning activities continues to grow with more coming this month! Interactive, self-guided online learning includes:

- The Role of the Regulatory Writer
- Drug Development Essentials: Regulatory Documents for Developing Clinical Studies and Reporting Clinical Data
- Drug Development Essentials: Regulatory Documents for Getting a Drug to Market and Monitoring Safety
- Ten Characteristics of Effective Tables and Graphs
- Harness the Power of EndNote: Manage Your Library's Data

Regulatory Writing Overview package – Jump-start a career in regulatory writing with this three-part online learning activity. Save over 15% by purchasing all three activities as a package. Learn more at www.amwa.org/regulatory123.

A Career in Medical Communication: Steps to Success – Designed to answer the most frequently asked questions about becoming a medical writer, this online learning activity will explore what medical communicators do, where they work, and the variety of documents they produce. Explore further at www.amwa.org/careersteps.

Find these activities, archived recordings of AMWA Live Webinars, Pocket Trainings, and more in AMWA Online Learning at www.amwa.org/online_learning.

Upcoming webinars:

July 27, 2016 | 1:00 PM EST - 2:00 PM ET
CORE Reference: A Medical Writer's Guide to Preparing CSRs in an Evolving Context
http://www.amwa.org/calendar_day.asp?date=7/27/2016&event=1605
Complimentary Webinar

August 24, 2016 | 1:00 PM EST - 2:00 PM ET
Medical Writers Heart Health Literacy
http://www.amwa.org/calendar_day.asp?date=8/24/2016&event=1604

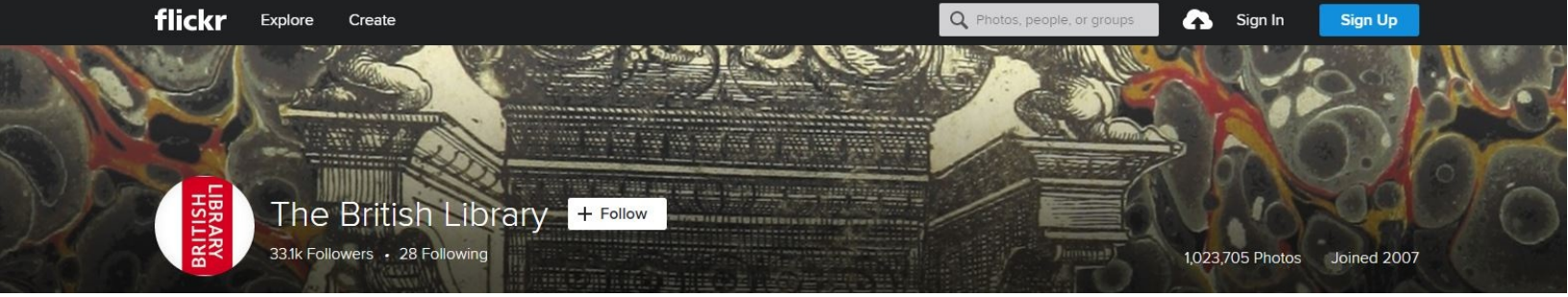
September 8, 2016
Unlock the Secrets to Freelance Success: Getting the Clients You Deserve
http://www.amwa.org/calendar_day.asp?date=9/8/2016&event=1599

Visit the AMWA Event Calendar (http://www.amwa.org/calendar_list.asp) for a full list of upcoming events.

MWC –
Next exam administration, October 6, 2016 in Denver, CO, in conjunction with the Medical Writing & Communication Conference. Application information at: http://www.amwa.org/mwc_apply

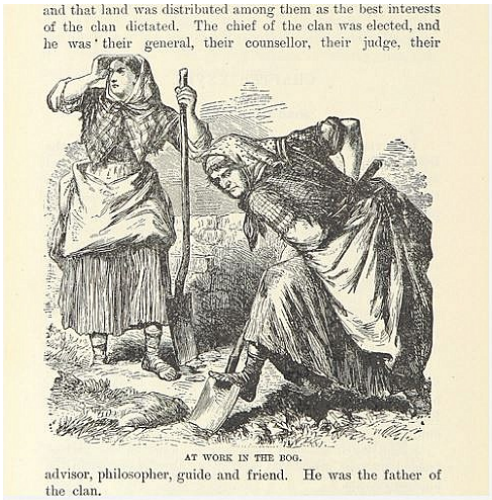
Essential Skills package
Purchase all 7 Self-Study Workbooks and earn the AMWA Essential Skills certificate at your own pace. Certificate enrollment is included. http://www.amwa.org/es_express

Package sale price: $950 member/$1,250 nonmember
ES Express Package offers over 25% in savings!



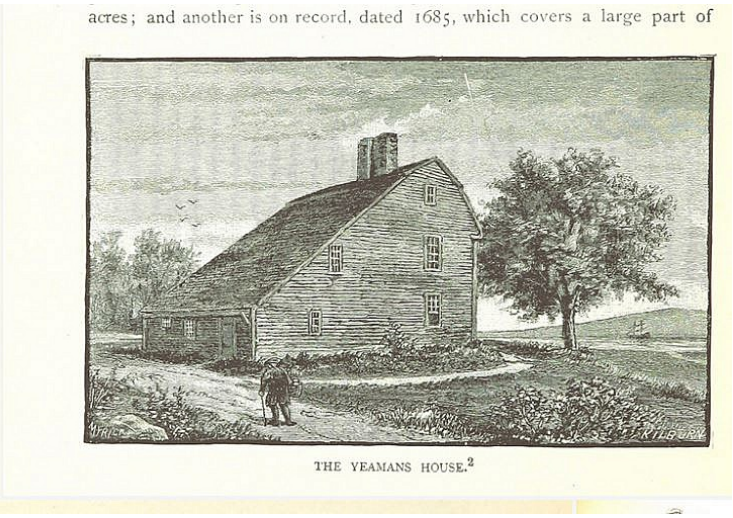
Backpage

British Library's Collection on Flickr


and that land was distributed among them as the best interests of the clan dictated. The chief of the clan was elected, and he was 'their general, their counsellor, their judge, their

AT WORK IN THE BOG.

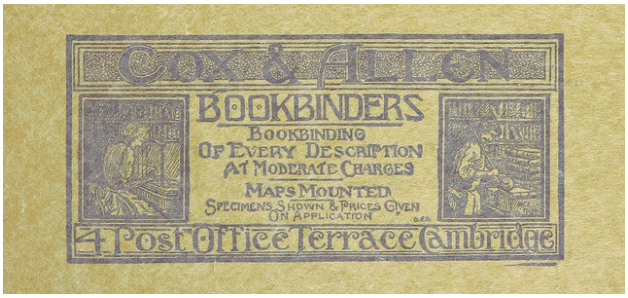
advisor, philosopher, guide and friend. He was the father of the clan.


acres; and another is on record, dated 1685, which covers a large part of

THE YEAMANS HOUSE.[2]

The British Library, created in 1973, is the home of over 13 million books, 310,000 manuscripts (of Jane Austen, Handel, the Beatles, and others), 920,000 journals and newspapers, 60 million patents, 8 million stamps, 4 million maps, 3 million sound recordings, and drawings--totaling 150 million items, with 3 million new items being added each year. The Library receives (by law) and holds a copy of every publication produced in the United Kingdom and Ireland.

The Sound Archive of the British Library has recordings from 19th-century cylinders to CDs, DVDs and MP3s. The Library's treasures include the Magna Carta, the Beatles' manuscripts, Leonardo da Vinci's notebooks and the Lindisfarne Gospels.



Every day, 160,000 people use British Library resources (online or on-site) and 400,000 visit the library every year.

Since 2007, the Library has been adding images from medival books, maps, advertisement collections, etc, at Flickr for the public to explore the Library's collection. Currently, there are over 1 million photos in the British Library's Flickr photostream. These images are in public domain and are an interesting place to go treasure hunting or finding old advertisements!

Sources:

BL Website: www.bl.uk
Flickr photostream: www.flickr.com/photos/britishlibrary/
Wikipedia: https://en.wikipedia.org/wiki/British_Library